



## PATENT APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q67541

Noboru YAMAJI, et al.

Appln. No. 10/009,332

Group Art Unit: 1614

Confirmation No.: 3848

Examiner: Not Yet Assigned

Filed: December 10, 2001

For: NOVEL METALLOPROTEASE HAVING AGGRECANASE ACTIVITY

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## EXCESS CLAIM FEE PAYMENT LETTER

Commissioner for Patents  
Washington, D.C. 20231

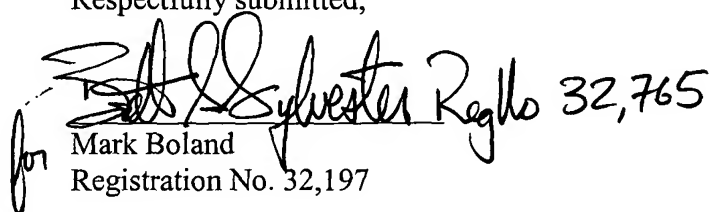
Sir:

A Preliminary Amendment is attached hereto for concurrent filing in the above-identified application. The resulting excess claim fee has been calculated as shown below:

	After Amendment		Highest No. Previously Paid For						
All Claims	34	-	25	=	9	X	\$18.00	=	\$162.00
Independent	4	-	4	=		X	\$84.00	=	\$0.00
TOTAL								=	\$162.00

A check for the statutory fee of \$162.00 is attached. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this letter is enclosed.

Respectfully submitted,

SUGHRUE MION, PLLC  
2100 Pennsylvania Avenue, N.W.  
Washington, D.C. 20037-3213  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860for   
Mark Boland  
Registration No. 32,197

Date: July 26, 2002



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**SUBMISSION OF ENGLISH TRANSLATION OF  
INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

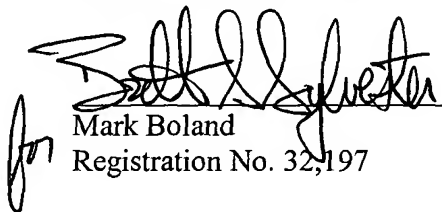
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Attached please find a copy of an English Translation of the International Preliminary Examination Report received from the Applicants, to advance prosecution in the event such is not readily available from the International Bureau. Claims 1-11 of the **PCT** application were found to be novel, involve an inventive step and include industrial applicability.

Respectfully submitted,

SUGHRUE MION, PLLC  
2100 Pennsylvania Avenue, N.W.  
Washington, D.C. 20037-3213  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

  
for Mark Boland  
Registration No. 32,197

Date: July 26, 2002

# PATENT COOPERATION TREATY

PCT/JP00/07917  
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## PCT NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 72.2)

From the INTERNATIONAL BUREAU

To:

NAGAI, Shozo  
Yamanouchi Pharmaceutical Co., Ltd.  
Patent Dept.  
17-1, Hasune 3-chome  
Itabashi-ku, Tokyo 174-8612  
JAPON

**TECH CENTER 1600/2900**

<b>Date of mailing (day/month/year)</b> 19 February 2002 (19.02.02)	
<b>Applicant's or agent's file reference</b> YK0029-PCT	<b>IMPORTANT NOTIFICATION</b>
<b>International application No.</b> PCT/JP00/07917	<b>International filing date (day/month/year)</b> 10 November 2000 (10.11.00)
<b>Applicant</b> YAMANOUCHI PHARMACEUTICAL CO., LTD. et al	

### 1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

### 2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

EP,AT,CA,CH,CN,FI,NO,NZ,RO,RU,SK,US

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AP,EA,AE,AG,AL,AM,AU,AZ,BA,BB,BG,BR,BY,BZ,CR,CU,CZ,DE,DK,DM,DZ,EE,ES,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,PL,PT,SD,SE,SG,SI,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW,OA

### 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. (41-22) 740.14.35	<b>Authorized officer</b>  A.ZOLTANSKI  Telephone No. (41-22) 338.83.38
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Translation

PATENT COOPERATION TREATY

87

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference YK0029-PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/07917	International filing date (day/month/year) 10 November 2000 (10.11.00)	Priority date (day/month/year) 11 November 1999 (11.11.99)
International Patent Classification (IPC) or national classification and IPC C12N 9/48, 15/57, 5/10, C07K 16/40, C12Q 1/34, A61K 38/48, A61P 19/02		
Applicant YAMANOUCHI PHARMACEUTICAL CO., LTD.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input checked="" type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand 11 May 2001 (11.05.01)	Date of completion of this report 31 July 2001 (31.07.2001)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/07917

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_ 1-41 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_ 1-11 \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages \_\_\_\_\_ 1-8 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages \_\_\_\_\_ 1-27 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/07917

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

**2. Citations and explanations**

Document 1: C.R. Flannery et al., Expression of ADAMTS homologues in articular cartilage, Biochem Biophys Res. Commun. (July 1999), Vol. 260, pages 318-322

Document 2: I. Abbazade et al., Cloning and characterization of ADAMTS11, an aggrecanase from ADAMTS family, J. Biol. Chem. (August 1999), Vol. 274, pages 23443-23450

Document 3: M.D. Tortorella et al., Purification and cloning of aggrecanase-1: a member of the ADAMTS family of proteins, Science (June 1999), Vol. 284, pages 1664-1666

The subject matters of claims 1-11 appear to involve an inventive step in view of documents 1-3 cited in the ISR. Documents 1-3 do not describe the metalloprotease having aggrecanase activity containing the amino acid sequences No. 213 to 583 of the amino acid sequences represented by Sequence ID No. 1 and a person skilled in the art could not have easily arrived at the invention on the basis of documents 1-3.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP00/07917

## VI. Certain documents cited

### 1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO 00/53774 A2 E,X	14 September 2000 (14.09.2000)	08 March 2000 (08.03.2000)	08 March 1999 (08.03.1999)

### 2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>